Innovative Medical Technology Overview: *Number 007/2016*

This IMTO review document describes an impartial review of the strengths and weaknesses of the submission by **Bruin Biometrics Europe Ltd** regarding the following medical technology.

SEM SCANNER

Overview of technology

SEM Scanner is a device intended to assist in the detection of pressure induced tissue damage. The SEM Scanner is a class IIa, non-invasive, hand held, portable device that interrogates the skins' underlying tissue to detect changes in sub-epidermal moisture (SEM). SEM is stated to be a biophysical marker associated with localised tissue oedema and to indicative of pressure induced tissue damage.

The SEM Scanner uses an integrated sensor that emits a low frequency current to measure relative tissue capacitance (ability to store electronic charge) – which is then turned into a calibrated SEM value. An increase in the presence of moisture (i.e. localised tissue oedema) leads to an increase in tissue capacitance and therefore a higher SEM value.

Comparator(s) and use in pathway of care

The SEM Scanner is to be used as an adjunct to the current standard of care (in all care settings). It should be noted that the evidence presented within the manufacturer's submission is drawn from the acute care, community hospital and nursing home settings.

Standard of care currently requires the identification of pressure ulcers using clinical judgement gained through skin assessment combined with an assessment of risk factors for pressure ulceration. However, there appears to be variation across NHS Scotland in terms of best practice for pressure ulcer risk assessment, which includes the application of visual inspection alongside risk assessment tools such as the Waterlow and Braden scales. More specifically, there are uncertainties across NHS Scotland relating to incomplete use of assessment tools and variation in the frequency of assessment.

In terms of the use within the current pathway, the manufacturer recommends that the SEM Scanner should be used (in addition to standard of care); 1) upon admission, 2) during the patients stay, and 3) at discharge. Clinical experts confirmed the positioning noting that the SEM Scanner is likely to be used on admission and then regularly throughout the patient's stay as per standard practice and level of patient risk. It has also been confirmed by clinical experts that approximately 14 readings per patient should be taken. The readings are manually written down and the lowest reading for each site is then subtracted from the highest reading which provides the result. A deviation over 0.6 suggests early inflammation in the sub epidermal layer suggesting possibility of imminent pressure damage.

According to the majority of clinical experts, the SEM Scanner is the only device to offer information to support medical staff in the assessment of unseen pressure ulcer development. There do appear to be other commercial devices available that detect skin moisture levels, however these are not marketed for use in the detection of pressure ulcers.

Product performance

As part of the regulatory approval process for the SEM Scanner, the manufacturer had developed a clinical evaluation report which included data to support the following; SEM is an indicator of pressure induced tissue damage, the SEM Scanner detects changes in SEM values in human tissue, and the SEM Scanner is reliable and easy to use. Also within the clinical evaluation report, the manufacturer carried out assessments to establish that spatial deviation in SEM readings – rather than using a single SEM reading versus a control value - was reliable and effective for distinguishing damaged tissue from undamaged tissue in subjects with and without pressure ulcers.

A key outcome surrounding the product performance of the SEM Scanner relates to the ability of scanner to reduce the incidence rate of pressure ulcers.To support the manufacturers claims around this outcome measure, three 'pre and post' independent case studies (UK care settings) were presented.

The first of these was an evaluation carried out in Farnham Community Hospital (Surrey, UK) in October 2015, where the SEM Scanner was introduced alongside standard of care (which includes the Waterlow risk assessment tool) for pressure ulcer risk assessment. The evaluation sought to identify the impact of the SEM Scanner on pressure ulcer rates. Patients in the study were frail/elderly patients recovering from acute care (or in step-up care) and neuro-rehab patients of all ages. Over the six month pilot period, there was found to be a 95% reduction in the number of pressure ulcers compared with the same period the previous year. Owing to a pending publication of the case study, the full data to support the headline conclusions above are not yet available. However, hospital colleagues provided a statement to ratify the manufacturer's claims surrounding the product performance of the SEM Scanner within the study.

The second evaluation was a three-month pilot of the use of the SEM Scanner in James Cook University Hospital (Middlesborough, UK). The hospital is one of two regional trauma centres and has a high proportion of patients over the age of 65 presenting with a traumatic hip fracture – a risk factor in the development of pressure ulcers (Haleem et al, 2008). During the pilot, where possible, all hip fracture patients were scanned (exceptions included patients with cognitive impairment or need for stabilisation) with the SEM Scanner on admission, and then on a daily basis as part of patients' scheduled skin assessments. The pilot was carried out from the start of September to the end of November 2015, on a ward where the average hospital acquired pressure ulcer (HAPU) incidence was 5 cases per month over the previous 12 month period. During the pilot, the average HAPU incidence was 2.6 cases per month. In the latter half of the pilot, the ward achieved 36 days HAPU-free, which increased to 72 days beyond the pilot period. The results of the study suggest that the SEM Scanner is a useful addition to the standard of care assessment. Further, the relative improvement in the latter stages of the trial suggests that there may be a learning curve to fully utilising the SEM Scanner readings.

The third evaluation was carried out within the Royal Albert Edward Infirmary (Wigan, UK), an acute care hospital. Patients across Orthopaedic Trauma and Intensive Care Units were assessed during a 45 day evaluation period, and were scanned upon admission and throughout their stay as part of their usual skin care assessment. Over the previous 10 months, the number of hospital acquired pressure ulcers had remained fairly stable within the units at 5-6 each month. Following implementation of the SEM Scanner, the results from the study found that - over the 45 days and based on the data from 62 discharged patients - zero pressure ulcers had developed.

In terms of impact on time to detection of pressure ulcers, the manufacturer presented studies by Bates-Jensen that assessed the use of SEM as a marker of pressure induced tissue damage in long-stay nursing home residents. Bates-Jensen's conclusions supported SEM as a valid measure of tissue injury and as a potential 'predictor' of pressure ulcers, approximately one week earlier than visual and risk assessment alone. In addition, a thesis by O'Brien compared nurses' visual assessments of pressure ulcers with assessments using the SEM Scanner. Data were collected

over 20 days from 47 at-risk adults. 16 (34%) patients exhibited sustained elevated deviation in SEM levels. Of these, 100% went on to develop visual signs of pressure ulcers. It is worth noting that mean SEM deviations exceeded the 0.5 threshold for all patients, and ranged from 0.7 to 2.1. The mean number of days for a nurse to visually detect damage was 5 days, whereas the SEM Scanner detected tissue damage at 1.1 days, a 3.9 day improvement over visual assessment alone.

The results of the Bates-Jensen and O'Brien studies form the basis of the manufacturers claim that the SEM Scanner is able to detect where skin is already damaged before this damage becomes visible as a pressure ulcer, which gives nurses extra information on which patients are most at risk providing extra time to deliver targeted care which can reverse the damage and prevent ulceration.

Safety

The SEM Scanner is contraindicated for use on broken skin.

Since product launch of the SEM Scanner in limited quantities in the European Union, no incidents have been reported with the SEM Scanner. Furthermore, no adverse events have been observed from use of the device during the clinical studies conducted thus far. No reports of complaints have been received.

Potential risks associated with the SEM Scanner include, a) the risk associated with cross contamination (as a result of improper disinfection), and b) the risk of false negative and false positive results.

To address the first of these risks, the manufacturer has developed and validated a detailed cleaning and disinfection standard procedure. The procedure is provided as part of the Instructions for Use, within a detailed Cleaning and Disinfection Procedure. The manufacturer has also confirmed that the procedures surrounding the SEM Scanner adhere to the Health Protection Scotland cleaning and disinfection procedures outlined in the National Infection Prevention and Control Manual (NIPCM). It is also worth noting that the majority of clinical experts did not anticipate the need to clean and disinfect the device between uses on different sites of the same patient.

In the event of false positives (that is, a reading from the SEM Scanner that indicated that pressure ulcer damage was present when in fact, damage was not present) or false negatives (a reading from the SEM Scanner showing the patient as not having damage, when in fact they were damaged), it is argued that the patient would be no worse off than under current standard of care. In the event of false positives, patients would receive inexpensive and unobtrusive preventative care. In the event of false negatives, patients will still be assessed using standard of care.

Strengths and limitations of the evidence

The strengths of the submitted evidence relate to the growing body of evidence that the SEM Scanner is a useful additional to standard of care for a more timely and accurate patient diagnosis of pressure ulcer development. Before and after studies are relatively inexpensive to undertake, and do allow for a quick 'answer' to a research question. Early identification of the damaged tissue appears to facilitate targeted care which may help reverse the damage, preventing pressure ulcer development.

There are some key weaknesses associated with the submitted data. Across all studies relating to the impact of the SEM Scanner on pressure ulcers incidence rates, very limited information is provided on the methodology of each study – particularly around patient group selection processes and data collection. The studies were observational by nature, and the control arms of the studies appear to have been based simply on the premise that the patients on the ward in the months prior to the intervention had similar characteristics to the patients receiving the intervention. In order to

identify an unbiased treatment effect, steps would need to be taken to ensure the control group was equivalent to the intervention group.

A further risk of bias is introduced owing to a lack of blinding in the studies - although this would be very difficult to guard against. For example, nurses undertaking the SEM Scanner assessment might alter their standard wound assessment and management processes as a result of simply having the scanner. The greater focus on pressure ulcers alone may affect the detection of the potential ulcers, rather than the SEM Scanner per se.

Other weaknesses include the small patient numbers, the generalisability of the study settings, and the relatively small follow-up period across all studies. However, in relation to the generalisability of the study settings, the varied practice across NHS Scotland contributes to this challenge.

Economic considerations

The cost of the SEM Scanner, before discounts, is approximately £14,000 per unit, with the device warranted for three years of regular daily usage. The manufacturer notes that the components are likely to have useful life beyond this period, although this has not been tested beyond the warranty period.

The manufacturer offers a number of procurement options for NHS Scotland; 1) capital purchase, 2) rental agreement, 3) operating lease, and 4) a shared risk model which ties most of the cost of the device to a measured successful impact.

In order to demonstrate the cost effectiveness of the SEM Scanner, the manufacturer submitted a cost comparison model which assessed, for a hypothetical cohort of NHS Scotland's patients, the healthcare costs associated with pressure ulcers without the SEM Scanner versus the healthcare costs associated with pressure ulcers with the SEM Scanner in use. The analysis was carried out from an NHS perspective over a three year time horizon. The original model submitted by the manufacturer contained a number of optimistic assumptions, for example surrounding the expected impact of the SEM Scanner on pressure ulcer rate reduction and some of the cost data. Therefore a revised ward level analysis was conducted.

Within the model, the costs of treating pressure ulcers – broken down by grade of pressure ulcer - included both labour and material costs, based on data from published sources. Pressure ulcer incidence rate data (including by grade) were drawn from the literature, and then applied to NHS figures on the number of NHSS bed days and admissions per year. These data were then combined to estimate the total cost impact of pressure ulcers under the current standard of care.

In order to demonstrate the impact of the SEM Scanner, the intervention arm of the model included the cost of the SEM Scanner device alongside a reduced resource use – and thus a reduced resource cost - as a result of the SEM Scanner lowering the pressure ulcer incidence rate.

The model was based on the key assumption that the use of the SEM Scanner leads to a 50% reduction in pressure ulcers.

Other key assumptions are as follows;

- 16 bed ward, approx. 1600 admissions p/a
- Pressure ulcer incidence 3%, with approx. 50 PU per year prior to SEM Scanner use
- Grade 1 or Grade 2 pressure ulcers equate to 80% of all pressure ulcers.
- Purchase of 2 SEM Scanners with costs spread over three years.

The results of this model found that NHSS may realise a potential ward-level cost reduction in excess of £50,000 per year. Further sensitivity analysis demonstrate that even if the assumed

costs associated with each grade of pressure ulcer were halved, the SEM Scanner may still realise sufficient cost reductions to offset the cost of the scanner.

The key uncertainty associated with the analysis, however, is the assumption that the use of the SEM Scanner leads to a 50% reduction in pressure ulcer incidence. The evidence to support this claim is of low quality and quantity.

It is worth noting that the manufacturer has focussed on the relative cost impact of the SEM Scanner, and quality of life (QoL) data have not been presented within the submission. It may be reasonable to assume that the avoidance of pressure ulcers would lead to a net improvement in QoL for patients, particularly in reduced pain, avoidance of complications (e.g., infection) and shorter in-patient stays.

The results of the analysis suggest that the SEM Scanner may provide a cost effective solution for specific hospital wards within NHS Scotland i.e. wards with a high pressure ulcer incidence rate. However, owing to the limitations associated with the product performance data underpinning the economic model, there remains uncertainty surrounding the impact of the scanner on pressure ulcer incidence rates.

Organisational and patient issues

In June 2015 the Scottish Government announced an aim to reduce acquired grade 2 – 4 pressure ulcers in hospitals and care homes in Scotland by 50% by 2017.

Data are available which reveal inconsistency both in terms of the PU incidence reporting across Scotland and the standard of pressure ulcer care currently applied in Scotland. For example, anonymised Scottish Patient Safety Programme (SPSP) data shows variable reporting across sites – alongside the caveat that there is likely to be significant under reporting of pressure ulcers. Healthcare Improvement Scotland inspection reports note that in relation to pressure ulcers, there is variation in terms of risk assessment within the acute care setting i.e. visual inspection and the use of tools such as the Waterlow and Braden scales. Furthermore, specific concerns raised in the reports surrounding pressure ulcer risk assessment related to incomplete checklists, scores being incorrectly calculated and variation in the frequency of assessment.

Healthcare Improvement Scotland recently published standards for prevention and management of pressure ulcers. The manufacturer references the importance of Standard 3 relating to best practice in the assessment of risk for pressure ulcer development.

The manufacturer states that surface discoloration associated with Stage 1 pressure ulcers is less evident in patients with dark skin tones, supporting this with data to show that patients with dark skin tones have a lower prevalence of diagnosed early-stage pressure ulcers (Stage 1, 13%) compared to light and medium skin-toned individuals (Stage 1, 32% to 38%). As such, the manufacturer argues that the SEM Scanner would help reduce such inequalities by providing an objective non-visual skin damage assessment.

During the case study carried out in the James Cook Hospital, patients were said to be happy to be scanned daily. However, in cases where patient's level of pain had to be stabilised, scanning on admission was not always possible. Furthermore, patients with cognitive impairment, agitation or confusion may not be suitable for daily scanning.

In relation to staff views on the use of the device, Farnham Community Hospital (Surrey, UK) noted that feedback from nursing colleagues was positive; *'nurses overwhelmingly said they found the scanner easy to use and said it gave them really useful information to support decision-making about their patients' pressure ulcers'.* However, it is worth noting SHTG clinical expert responses which highlight the importance of nurse training in order to provide accurate results. Incorrect positioning of the device can lead to inaccurate results.

Summary

The evidence presented suggests that the SEM Scanner is an innovative device to assist nurses in the identification of early pressure ulcer development. There are data from three before and after studies to support the assumption that earlier identification through the use of the SEM Scanner may lead a reduction in pressure ulcer incidence rates. This in turn may result in resource reductions for NHS Scotland. However, there is a high risk of bias associated with the studies, which undermines the findings presented here.

Further development of the evidence base is therefore encouraged in order to bolster or otherwise the claims made by the manufacturer surrounding the product performance and cost effectiveness of the SEM Scanner. It would be particularly useful to test the device within a Scottish care setting with a high incidence of pressure ulcers.